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EXAMINER	
SHEIKH, HUMERA N	
ART UNIT	**PAPER NUMBER**
1615	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	02/15/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/537,553	MONIQUE BERWAER ET AL	
	Examiner	Art Unit	
	Humera N. Sheikh	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 January 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-7,14,16-21 and 38-44* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7,14,16-21 and 38-44* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *6/3/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of the Application

Receipt of the Preliminary Amendment, Applicant's Arguments/Remarks, the Information Disclosure Statement (IDS) and the Certified Copy of Foreign Priority Documents, all filed 06/03/05 is acknowledged.

Claims 1-7, 14, 16-21 and 38-44 are pending in this action. Claims 3-7, 14, 16-21, 38, 40 and 43 have been amended. Claims 8-13, 15, 22-37 and 45-48 have been cancelled. Claims 1-7, 14, 16-21 and 38-44 are rejected.

Inventorship

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or

improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-7, 14, 16-21 and 38-44 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-92 of U.S. Patent No. 7,014,867 ('867 Patent) in view of Weinstein *et al.* (U.S. Patent No. 6,051,585) ('585 Patent). Although the conflicting claims are not identical, they are not patentably distinct from each other because similar subject matter has been claimed in both the instant '553 application and the '867 Patent.

The only distinction observed between the instant '553 application and the '867 Patent is that the instant '553 application (a) claims a tablet comprising *efletirizine* and pseudoephedrine, whereas the '867 Patent claims a tablet comprising *cetirizine* and pseudoephedrine; (b) Generic claim 1 of the instant '553 application does not recite the interfacial surface area of the pseudoephedrine segment and cetirizine segment being less than 180 mm^2, whereas the '867 Patent recites the interfacial surface area in it's claim 1; (c) the instant '553 application claims the proviso that the tablet comprises less than 5% by weight, relative to the total weight of the *pseudoephedrine* segment, of an alkalinizing agent, whereas the '867 Patent claims the proviso

that the tablet comprises less than 5% by weight, relative to the total weight of the *tablet.* Asides from these distinctions, the inventions claimed in both the instant '553 application and the '867 Patent are essentially quite the same.

It is noted, however, with regard to subsection (b) above, that while the instant '553 application does not recite the interfacial surface area in it's generic claim 1, as does the '867 Patent, the instant '553 application claims the same interfacial surface area in its' dependent claim 5.

It is also noted that the instant '553 application and the '867 Patent recite the same limitations of (a) the tablet being substantially free of impurities; and (b) also recite the proviso that the pseudoephedrine segment comprises less than 5% by weight, relative to the total weight of the pseudoephedrine segment, of an alkalinizing agent (see instant claim 7 & claim 5 of the '867 Patent).

In addition, it is noted that both the instant '553 application and the '867 Patent both claim the same 'area under the plasma drug concentration versus time curve' range. Claims 20 & 21 of the instant '553 application correspond to claims 18 & 19 of the '867 Patent.

The Examiner acknowledges that the instant '553 application and the '867 Patent utilize different antihistamines (efletirizine vs. cetirizine). However, it would have been *prima facie* obvious to one of ordinary skill in the art to employ *any* suitable or effective antihistamine with the expected result of providing for antihistaminic properties targeted for the treatment of the common cold, rhinitis, flu and the like. The '585 Patent is cited to demonstrate an antihistamine/decongestant formulation for treating rhinitis whereby a decongestant,

pseudoephedrine is provided in combination with any of suitable antihistamines, such as cetirizine, loratidine or fexofenadine (see column 3, lines 25-33).

Additionally, it would have been obvious to one of ordinary skill in the art to vary and determine suitable amounts of alkalinizing agent, based on either, the total weight of the tablet or based on particular segments (*i.e.,* pseudoephedrine segment) of the tablet, through the use of routine or manipulative experimentation to obtain optimal results, as these are variable parameters attainable within the art. Moreover, with regards to concentrations or amounts, the Examiner points out that generally, differences in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller,* 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

* * * * *

Claims 1-7, 14, 16-21 and 38-44 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 and 2 of copending Application No. 11/251,895 in view of Weinstein *et al.* (U.S. Patent No. 6,051,585) ('585 Patent). Although the conflicting claims are not identical, they are not patentably distinct from each other because similar subject matter has been claimed in both the instant '553 application and the copending '895 Application.

The only distinctions observed between the instant '553 application and the '895 copending application are (1) the instant '553 application claims *efletirizine* and pseudoephedrine, whereas the copending '895 application claims *cetirizine* and pseudophedrine; and (2) the instant '553 application claims that the *pseudoephedrine segment* comprises less than 5% by weight, relative to the total weight of the *pseudoephedrine* segment, of an alkalinizing agent (see claim 7 of '553), whereas the copending '895 application claims the proviso that the *tablet* comprises less than 5% by weight, relative to the total weight of the *tablet,* of an alkalinizing agent. Asides from these distinctions, the inventions claimed in both the instant '553 application and the copending '895 application are essentially quite the same.

It is also noted that claim 5 of the instant '553 application claims the same interfacial surface area of the pseudoephedrine segment and cetirizine segment being less than 180 mm^2 as is also claimed in claims 1 and 2 of the copending '895 application.

It would have been *prima facie* obvious to one of ordinary skill in the art to employ *any* suitable or effective antihistamine with the expected result of providing for antihistaminic properties targeted for the treatment of the common cold, rhinitis, flu and the like. The '585 Patent is cited to demonstrate an antihistamine/decongestant formulation for treating rhinitis whereby a decongestant, pseudoephedrine is provided in combination with any of suitable antihistamines, such as cetirizine, loratidine or fexofenadine (see column 3, lines 25-33).

Additionally, it would have been obvious to one of ordinary skill in the art to vary and determine suitable amounts of alkalinizing agent, based on either, the total weight of the tablet or based on particular segments (*i.e.,* pseudoephedrine segment) of the tablet, through the use of routine or manipulative experimentation to obtain optimal results, as these are variable

parameters attainable within the art. Moreover, with regards to concentrations or amounts, the Examiner points out that generally, differences in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller,* 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

* * * * *

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-7, 14, 16-21 and 38-44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Johnson *et al.* (U.S. Patent No. 6,171,618 B1) in view of Aslanian *et al.* (U.S. Patent No. 6,103,735).

The instant invention is drawn to a tablet comprising two distinct segments, one segment of which comprises as active ingredient predominantly efletirizine and a second segment of which comprises as active ingredient predominantly pseudoephedrine, said segments being composed and formed in such a way that the resulting tablet is substantially free of impurities formed by reaction of efletirizine with pseudoephedrine, and with the proviso that the tablet comprises less than 5% by weight, relative to the total weight of the pseudoephedrine segment, of an alkalinizing agent.

Johnson *et al.* ('618) teach a combination dosage form containing cetirizine as an immediate release component and pseudoephedrine or a pharmaceutically acceptable salt thereof as a controlled release component. The dosage form is free of alcohols having a molecular weight lower than 100 and reactive derivatives thereof (see Abstract); (col. 1, lines 10-12).

Cetirizine and pseudoephedrine are provided as a unitary dosage form, such as a tablet, that can be taken once-daily or twice-daily to improve convenience and ensure patient compliance. The dosage form is useful for the treatment of nasal congestion for the treatment of allergic rhinitis (col. 1, lines 35-54).

In one embodiment, the invention provides for a solid dosage form comprising cetirizine and pseudoephedrine wherein: at least a portion of the pseudoephedrine is contained in a core comprising said portion of pseudoephedrine, whereby release of said pseudoephedrine into an environment of use is sustained; and wherein said cetirizine is contained as an immediate release

component in said dosage form; and wherein said dosage form is substantially free of alcohols having a molecular weight lower than 100 and reactive derivatives thereof (col. 1, lines 57-67); (col. 2, lines 1-42). Johnson et al. teach that the dosage form should be substantially free of such reactive components at the time the immediate-release cetirizine component is introduced into the dosage form and thereafter (col. 3, lines 35-59).

Where a coating is employed, the immediate release cetirizine-containing coating layer is preferably coated over the entire surface of the core for convenience in formulating the tablet (col. 4, lines 28-66). In one dosage form embodiment, all of the cetirizine is incorporated into a separate (i.e., from the sustained release core) immediate release coating that surrounds the pseudoephedrine core of the dosage form, and all of the pseudoephedrine is incorporated into the core (col. 5, line 65 – col. 6, line 4).

Various excipients can be added, which include binders, lubricants and cellulosic materials for forming the membrane-coating layer (col. 9, line 25 – col. 12, line 18).

The amount of cetirizine administered will generally be in the range of about 5 to about 20 mg/day. The amount of pseudoephedrine administered will generally be in the range of about 60 to about 240 mg/day (col. 6, lines 12-22). These ranges meet the instant ranges claimed in claim 16.

Johnson *et al.* teach that generally, the cetirizine should be at least 80% released from the dosage form within an hour after administration (col. 3, lines 7-9). The pseudoephedrine, by contrast, releases in a sustained release fashion, wherein at least about 75% of the drug contained in the dosage form releases over a period of 4 to 36 hours (col. 3, lines 10-15).

While Johnson *et al.* do not explicitly teach all the claimed concentration ranges, the Examiner points out that generally, differences in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller,* 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

Johnson *et al.* teach a combination tablet comprising cetirizine and pseudoephedrine. Johnson et al. do not teach *efletirizine.*

Aslanian *et al.* ('735) teach a pharmaceutical composition useful for the treatment of allergic rhinitis, asthma and related respiratory disorders comprising a therapeutically effective amount of (i) at least one neurokinin antagonist; (ii) at least one H_3 antagonist and (iii) at least one H_1 antagonist, whereby suitable H_1 antagonists taught include *efletirizine* and cetirizine (see Abstract; col. 1, line 8 – col. 2, line 16); (col. 5, line 55 – col. 6, line 7). The pharmaceutical composition can additionally contain a decongestant, such as pseudoephedrine (col. 2, lines 16-25).

The compositions may be formulated in sustained release form to provide the rate-controlled release of any one or more of the components or active ingredients to optimize therapeutic effects, *i.e.*, neurokinin antagonism, antihistaminic activity and the like (col. 6, lines 45-49).

Suitable dosage forms for sustained release include layered tablets containing layers of varying disintegration rates or controlled release polymeric matrices (col. 6, lines 50-55).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to employ *any* suitable or effective antihistamine, particularly efletirizine as taught by Aslanian *et al.* within the pharmaceutical compositions of Johnson *et al.*. One of ordinary skill in the art would be motivated to do so with a reasonable expectation of success because Aslanian *et al.* teach a combination, layered tablet comprising suitable antihistamines such as efletirizine and teach that the antihistamines aid in providing for the treatment of allergic rhinitis and related respiratory disorders. The expected result would be an improved, highly effective drug formulation that offers enhanced antihistaminic properties for combating respiratory disorders and diseases.

Pertinent Art:

Prior Art made of record, not relied upon and cited of interest:

- Weinstein *et al.* (U.S. Patent No. 6,051,585) (04/2000):

  Weinstein et al. teach a single-dose antihistaming/decongestant formulation for the treatment of rhinitis (see column 3, lines 25-45).

- Kreutner *et al.* (U.S. Patent No. 5,869,479):

  Kreutner et al. teach compositions for treating upper airway allergic responses comprising H_1 receptor antagonists, such as efletirizine (see column 2, lines 47-65).

Conclusion

-- No claims are allowed at this time.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Humera N. Sheikh whose telephone number is (571) 272-0604. The examiner can normally be reached on Monday through Friday during regular business hours.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have any questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

HUMERA N. SHEIKH
PRIMARY EXAMINER

Art Unit 1615

February 04, 2007

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